

**VITAMIN, MINERAL, AND OTHER PRODUCTS OF SPECIAL DIETARY SIGNIFICANCE\***

**12995. Alleged adulteration and misbranding of vitamin tablets. U. S. v. Michael Walsh (Kelp Laboratories).** Defendant's motion granted to dismiss on grounds that guaranty provision of the law applies only to a guaranty that is false relative to an interstate shipment. On appeal to United States Supreme Court, judgment of District Court overruled and case remanded. Defendant's motion granted to dismiss on other grounds. (F. D. C. No. 17829. Sample No. 31202-H.)

**INFORMATION FILED:** April 25, 1946, Southern District of California, against Michael Walsh, trading as Kelp Laboratories, San Diego, California. The defendant was charged with giving a false guaranty, the facts of which appear in the opinion.

**LABEL, IN PART:** "Harrison Formula B \* \* \* Ingredients: Vitamin B<sub>1</sub>, Riboflavin (Vitamin G), Niacinamide, Brewers Yeast, Whey \* \* \* Six Tablets daily furnish \* \* \* 10 mg. Niacinamide."

**NATURE OF CHARGE:** Adulteration, Section 402 (b) (1), a valuable constituent, niacinamide, had been omitted, since six tablets of the food would provide less than 10 milligrams of niacinamide.

Misbranding, Section 403 (a), the label statement "Six Tablets \* \* \* furnish \* \* \* 10 mg. Niacinamide" was false and misleading.

**DISPOSITION:** On June 14, 1946, the defendant filed a motion to dismiss on the grounds that the guaranty provision of the Federal Food, Drug, and Cosmetic Act applies only to a guaranty that is false relative to an interstate shipment. The motion was granted by the District Court on July 11, 1946.

On October 17, 1946, a notice of appeal to the Supreme Court of the United States was filed, and on May 19, 1947, the following opinion was handed down, reversing the judgment of the District Court:

**JUSTICE MURPHY:** "This appeal brings before us § 301 (h) of the Federal Food, Drug, and Cosmetic Act of 1938, 52 Stat. 1040, 1042, 21 U. S. C. § 331 (h), which prohibits the giving of a false guaranty that any food, drug, device or cosmetic is not adulterated or misbranded within the meaning of the Act.

"Appellee does business in San Diego, California, under the name of Kelp Laboratories. An information has been filed, charging appellee with having given a false guaranty in violation of § 301 (h). The following facts have been alleged: In February, 1943, appellee gave a continuing guaranty to Richard Harrison Products, of Hollywood, California, stating that no products thereafter shipped to the latter would be adulterated or misbranded within the meaning of the Act. On February 24, 1945, while the guaranty was in full force and effect, appellee consigned to Richard Harrison Products, at Hollywood, a shipment of vitamin products which were allegedly adulterated and misbranded—thereby making the guaranty false in respect of that shipment. Prior and subsequent to the date of the shipment, Richard Harrison Products was engaged in the business of introducing and delivering for introduction into interstate commerce quantities of the vitamin products supplied by appellee.

"Appellee moved to dismiss the information on the ground that it did not state an offense. The argument was that § 301 (h) applies only to a guaranty that is false relative to an interstate shipment, whereas the alleged shipment here was to a consignee within California, the state of origin, and there was no allegation that the consignee purchased the order for someone outside California or that it intended to sell the products in its interstate rather than its intrastate business. The District Court gave an oral opinion sustaining appellee's contention and granting the motion to dismiss. The case is here on direct appeal by the United States.

"The Federal Food, Drug, and Cosmetic Act rests upon the constitutional power resident in Congress to regulate interstate commerce. To the end that the public health and safety might be advanced, it seeks to keep interstate channels free from deleterious, adulterated and misbranded articles of the specified types. *United States v. Dotterweich*, 320 U. S. 277, 280. It is in that interstate setting that the various sections of the Act must be viewed.

"But § 301 (h), with which we are concerned, does not speak specifically in interstate terms. It prohibits the 'giving of a guaranty or undertaking re-

\*See also No. 12862.

ferred to in section 303 (c) (2), which guaranty or undertaking is false,' the only exception being as to a false guaranty given by a person who, in turn, relied upon a similar guaranty given by the person from whom he received in good faith the adulterated or misbranded article.<sup>1</sup> Nothing on the face of the section limits its application to guaranties relating to articles introduced or delivered for introduction into interstate commerce. From all that appears, its proscription plainly extends to the giving of any false statutory guaranty, without regard to the interstate or intrastate character of the shipment in question, to those who are engaged in the business of making interstate shipments.

"Nor do we find any interstate limitation of the type which appellee proposes in the reference made in § 301 (h) to § 303 (c) (2).<sup>2</sup> That reference is made simply to define the type of guaranty or undertaking the falsification of which is prohibited by § 301 (h). Instead of spelling out the matter, § 301 (h) adopts the reference in § 303 (c) (2) to 'a guaranty or undertaking signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the article, to the effect . . . that such article is not adulterated or misbranded, within the meaning of this Act, designating this Act.' The fact that § 303 (c) (2) relieves a holder of such a guaranty from the criminal penalties provided by § 303 (a) for violating § 301 (a) does not carry over the interstate limitation of § 301 (a) to § 301 (h). Section 301 (a) prohibits the introduction or delivery for introduction into interstate commerce of illicit articles,<sup>3</sup> and § 303 (c) (2) relieves one from the liabilities of such introduction if one has a guaranty or undertaking as therein described. Section 301 (h) has adopted that description for the entirely different purpose of informing persons what kind of a guaranty or undertaking may not be given falsely. In other words, § 301 (a) is directed to illegal interstate shipments, while § 301 (h) is directed to the giving of false guaranties. Guaranties as described in § 303 (c) (2) may be used by interstate dealers in connection with either interstate or intrastate shipments and those guaranties that are false are outlawed by § 301 (h).

"It is true, of course, that the guaranty referred to in § 303 (c) (2) is one given for the purpose of protecting the dealer 'in case of an alleged violation of section 301 (a),' thereby relieving him of liability if he reships adulterated or misbranded goods in interstate commerce. But where such a guaranty, as in this case, is given to a dealer regularly engaged in making interstate shipments and who may therefore have need of the guaranty, § 301 (h) imposes liability on the guarantor if that guaranty turns out to be false. And that liability attaches even where the particular shipment which renders the guaranty false is not alleged to have been an interstate one.

"It is significant that § 301 (h) had no counterpart in the predecessor statute, the Food and Drugs Act of 1906, 34 Stat. 768. Under § 9 of that Act, a dealer could not be prosecuted for shipping adulterated or misbranded articles in interstate commerce if he had a guaranty of a type similar to that referred to in the present statute. If there were such a guaranty, the guarantor was subject to the penalties which would otherwise attach to the dealer. The result was that the guarantor was not liable on account of a false guaranty unless the dealer had shipped the prohibited article in interstate commerce. *Steinhardt Bros. & Co. v. United States*, 191 F. 798, 800; *United States v. Charles L. Heinle Specialty Co.*, 175 F. 299, 300-301. There was no liability for issuing a false guaranty as such to one engaged in an interstate business. But in the

<sup>1</sup> Section 301 (h) prohibits "The giving of a guaranty or undertaking referred to in section 303 (c) (2), which guaranty or undertaking is false, except by a person who relied upon a guaranty or undertaking to the same effect signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the food, drug, device, or cosmetic; or the giving of a guaranty or undertaking referred to in section 303 (c) (3), which guaranty or undertaking is false."

<sup>2</sup> Section 303 (c) (2) provides that no person shall be subject to the penalties of § 303 (a) "for having violated section 301 (a) or (d), if he establishes a guaranty or undertaking signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the article, to the effect, in case of an alleged violation of section 301 (a), that such article is not adulterated or misbranded, within the meaning of this Act, designating this Act, or to the effect, in case of an alleged violation of section 301 (d), that such article is not an article which may not, under the provisions of section 404 or 505, be introduced into interstate commerce."

<sup>3</sup> Section 301 (a) prohibits "The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded."

1938 Act, Congress added a new liability in the form of § 301 (h), making the guarantor liable for giving a false guaranty of the type referred to in § 303 (c) (2). We find it impossible to say that the framers of the 1938 Act added § 301 (h) for the useless purpose of achieving the same result as had been reached under the 1906 Act without such a provision.

"We thus conclude that § 301 (h) definitely proscribes the giving of a false guaranty to one engaged wholly or partly in an interstate business irrespective of whether that guaranty leads in any particular instance to an illegal shipment in interstate commerce. Such a construction is entirely consistent with the interstate setting of the Act. A manufacturer or processor ordinarily has no way of knowing whether a dealer, whose business includes making interstate sales, will redistribute a particular shipment in interstate or intrastate commerce. But if he guarantees that his product is not adulterated or misbranded within the meaning of the Act, he clearly intends to assure the dealer that the latter may redistribute the product in interstate commerce without incurring any of the liabilities of the Act. And the dealer is thereby more likely to engage in interstate distribution without making an independent check of the product. The possibility that a false guaranty may give rise to an illegal interstate shipment by such a dealer is strong enough to make reasonable the prohibition of all false guaranties to him, even though some of them may actually result only in intrastate distribution. By this means, some of the evils which Congress sought to eliminate are cut down at their source and the effectiveness of the Act's enforcement is greatly enhanced.

"So construed, § 301 (h) raises no constitutional difficulties. The commerce clause of the Constitution is not to be interpreted so as to deny to Congress the power to make effective its regulation of interstate commerce. Where that effectiveness depends upon a regulation or prohibition attaching regardless of whether the particular transaction in issue is interstate or intrastate in character, a transaction that concerns a business generally engaged in interstate commerce, Congress may act. Such is this case.

"The judgment of the District Court is accordingly *Reversed*."

JUSTICE JACKSON, *dissenting*: "Stretch the Food and Drugs Act as we will, I cannot make it cover this charge as a crime. The statutory scheme is to make a crime of 'The introduction or delivery for introduction into interstate commerce' of adulterated or misbranded goods. 52 Stat. 1042, 21 U. S. C. § 331 (a) and (d).

"But since many shippers buy goods of others and do not know their precise ingredients, Congress allowed an escape for the violator, provided he acted in good faith and could trace the responsibility to another. This he must do by producing a signed guaranty or undertaking, and the statute requires that it shall be conditioned 'to the effect, *in case of an alleged violation of § 331 (a)*, that such article is not adulterated or misbranded . . . or to the effect, *in case of an alleged violation of § 331 (d)*, that such article is not an article' forbidden shipment by stated paragraphs of the Act. [Emphasis added.] 52 Stat. 1043, 21 U. S. C. § 333 (c).

"It will be noticed that Congress not only provided but repeated that the statutory bond required is 'in case of an alleged violation' by introducing or delivering for introduction of goods in interstate commerce. No such violation has been alleged here; these goods were never introduced or delivered for introduction into interstate commerce. But the Court seems to think it is enough that there are some grounds for expecting that this crime possibly, or probably, or perhaps pretty certainly, would eventually be committed.

"Of course, if the assured had committed this offense and had fallen back on the guarantor, the statute which reached the assured would not be sufficient. To punish the responsible person, it was made a crime to give a false guaranty 'referred to in' the statute. 52 Stat. 1042, 21 U. S. C. § 331 (h).

"The Government now seeks to exact criminal responsibility on a guarantee, expressly conditioned only 'in case of violation,' in a case of no violation. Until a violation is alleged, the guaranty plays no statutory role at all. It might afford a cause of action if false, but that is quite different from making it a crime. For it is no guaranty at all for criminal prosecution purposes if violation of neither § 331 (a) nor § 331 (d) is alleged. The statute requires such violation to be alleged only, not proved, in order to put the guarantor rather than the assured to the proof. This is the only instance I recall where the guar-

antor is liable when there is no breach of the condition of the bond. The whole plan was to have a substituted liability in case the violator of the Act became such in good faith. This decision makes a new, independent and original liability where there has been no alleged violation by moving the goods in interstate commerce.

"I do not think we should take such liberties in expanding a criminal statute in which the sovereign once was considered under a duty to be explicit and the subject entitled to the doubt."

On November 20, 1947, a new motion to dismiss having been filed in the District Court by the defendant, on the grounds that the Government had failed to furnish the defendant with a portion of the official sample, although required to do so by Section 702 (b) of the Federal Food, Drug, and Cosmetic Act, the motion was granted and the case was dismissed.

**12996. Alleged misbranding of Vitaminerals. U. S. v. 68 Bottles and 100 Printed Price Lists \* \* \*. Tried to the court. Verdict for claimant.**  
(F. D. C. No. 18988. Sample No. 12340-H.)

**LIBEL FILED:** January 18, 1946, District of Massachusetts. On April 22, 1946, the court ordered the case removed for trial to the Northern District of California.

**ALLEGED SHIPMENT:** On or about September 24, 1945, by the Vitaminerals Co., from Los Angeles, Calif. One hundred printed price lists were shipped separately on or about the same date.

**PRODUCT:** 68 bottles of Vitaminerals and 100 printed price lists at Boston, Mass. Examination of the product showed that it was a mixture of dextrose sugar, wheat germ, and a small amount of malt.

**NATURE OF CHARGE:** Misbranding, Section 403 (a), it was alleged that the statements on the bottle label and the printed price lists were false and misleading in that they represented and suggested that the article when used as directed was an effective aid in following a reducing diet, in preventing discomfort due to diminished food intake, and in curbing the appetite; and that the article was of no significant value for such purposes. It was alleged further that the label designation "Vitaminerals" was false and misleading, in that the article was not a significant source of vitamins and minerals needed by man, as the designation represented and suggested.

**DISPOSITION:** On September 3 and 4, 1947, the Vitaminerals Co., claimant, having filed an answer denying the material allegations of the libel, the case was tried to the court. On December 3 the court made the following findings of fact and conclusions of law and entered judgment for the claimant, dismissing the libel:

*HARRIS, District Judge:*

#### FINDINGS OF FACT

"1. That Claimant, Vitaminerals Co., did, on or about September 24, 1946, as alleged in the libel of information on file herein, ship in interstate commerce from Los Angeles, California, to Boston, Massachusetts, via Railway Express Agency, an article of food consisting of 68 bottles, more or less, labelled in part:

No. 5 Vitaminerals A palatable nutritional supplement composed of defatted, dehydrated wheat embryo, non-diatstatic malt, dextrose and vitamin B<sub>1</sub>, for use in a required low caloric diet as an aid in appeasing the appetite for excess food.

And via parcel post, on or about September 24, 1946, 100 printed price lists, more or less, entitled 'VITAMINERALS CO.'

"2. That thereafter the Marshal of the District Court of the United States for the District of Massachusetts, pursuant to the Libel of Information in this case, did seize said articles of food and said price lists, and the same are now in his possession or under his control.

"3. That Vitaminerals Co. did file a verified claim of ownership to the articles seized in the Complaint herein.

"4. That the Claimant, Vitaminerals Co., did file an Answer in the cause herein.

"5. That upon application of Claimant, Vitaminerals Co., said cause was transferred from the District Court of the United States for the District of